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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/527,344	03/17/00	DARBERICH T	4821-334-999

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EXAMINER	
BAHAR, M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/527,844	BARBERICH ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *16-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Applicant's response to the restriction requirement submitted August 28, 2001 (Paper No. 7) is acknowledged.

Applicant's election with traverse of the invention of Group I, claims 1-15, as well as the election of neuroleptic disorders as the specie, submitted August 28, 2001 is acknowledged. The traversal is on the ground(s) that at least Groups I and II should be examined together. Applicants' remarks have been considered in this regard but are not persuasive. As discussed in the restriction requirement of June 25, 2001, the inventions in Groups I and II are distinct from one another since a method of treating neuroleptic disorders, e.g. seizures, can be treated with a materially different composition containing phenytoin.

Claims 16-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claims 1-15 are herein examined on the merits in so far as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "preventing" in claims 1 and 3, renders the claims indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Examples of how and when to prevent "disorders ameliorated by inhibition of seratonin reuptake at 5-HT2 and/or inhibition of dopamine D2 receptors in a patient" are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those situations wherein prevention of disorders ameliorated by inhibition of seratonin reuptake at 5-HT2 and/or inhibition of dopamine D2 receptors would be effected. Furthermore, it is unclear as to the degree of prevention (e.g., total prevention, some prevention, probable prevention, etc.) herein because the specification does not disclose the extent of prevention achieved. Examiner would favorably consider the term "prophylaxis" over "prevention".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Geodon (Ziprasidone HCL).

Geodon (Ziprasidone HCL) teaches that Ziprasidone is a antipsychotic agent which exhibits high in vitro binding affinity for dopamine D2 and seratonin 5HT2A receptors, see particularly page 1. Geodon (Ziprasidone HCL) teaches that ziprasidone has been clinically tested in schizophrenic subjects, see pages 2 and 3, in particular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geodon (Ziprasidone HCL) in view of Prakash et al.

Geodon (Ziprasidone HCL) teaches that Ziprasidone is a antipsychotic agent which exhibits high in vitro binding affinity for dopamine D2 and seratonin 5HT2A receptors, see particularly page 1. Geodon (Ziprasidone HCL) teaches that ziprasidone has been clinically tested in schizophrenic subjects, see pages 2 and 3, in particular. Geodon (Ziprasidone HCL) teaches that the long-term dosage for ziprasidone is 20-80 mg BID, see page 19, maintenance treatment. Geodon (Ziprasidone HCL) also teaches that ziprasidone is administered orally, in capsule form, see description on page 1.

Geodon (Ziprasidone HCL) does not teach the employment of ziprasidone sulfone or ziprasidone sulfoxide in its method of treating neuroleptic disorders.

Prakash teaches that ziprasidone sulfone and ziprasidone sulfoxide are the major ziprasidone metabolites in human serum. Prakash also teaches that affinity of the said metabolites for 5-HT2 and D2 receptors are low in comparison with ziprasidone, see abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ ziprasidone sulfone and ziprasidone sulfoxide in a method of treating neuroleptic disorders.

One of ordinary skill in the art would have been motivated to employ ziprasidone sulfone and ziprasidone sulfoxide in a method of treating neuroleptic disorders because ziprasidone sulfone and ziprasidone sulfoxide are known metabolites of ziprasidone. Moreover, although ziprasidone sulfone and ziprasidone sulfoxide have lower affinity for 5-HT2 and D2 receptors than ziprasidone, they would nevertheless bind to the 5-HT2 and D2 receptors and would be expected to exhibit similar pharmacological activity to that of ziprasidone. Note that the percentage of these two metabolites are very low in comparison to the other 10 metabolites which could account for the [redacted] statement that such compounds are "unlikely to contribute to its (ziprasidone's) antipsychotic effects".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
September 6, 2001

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200